

Please enter the following amendments and remarks:

**STATUS OF THE CLAIMS**

Claims 1-9, 12-22, 24-31, 33, 34, 36, 38-40 and 42-91 are pending in the Application.

Claims 1-9, 12-22, 24-31, 33, 34, 36, 38-40 and 42-91 have been rejected by the Examiner.

Claim 12 has been canceled.

Claims 45-46, 51, 57, 64, and 84-85 have been amended.

Reconsideration of the present Application is respectfully requested.

**REMARKS**

Applicant acknowledges with appreciation that the objection to claim 20 has been withdrawn. Claims 51, 57, and 64 were objected to because of informalities. Claims 51, 57, and 64 have been amended, therefore, Applicant requests that said objections be withdrawn.

Claims 45-46 and 84-85 have been rejected under 35 U.S.C. §101. Claims 79-84 and 86-87 have been rejected under 35 U.S.C. 102(e) as being anticipated by Rosenblum (U.S. 6,529,801). Claims 1-2, 9, 14-21, 24-27, 29-31, 33-34, 36, 38-40, 42-50, and 90 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz et al. (U.S. 6,421,650) in view of Lion (U.S. 6,330,491). Claims 3-8, 22 and 28 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz et al. (U.S. 6,421,650) in view of Lion (U.S. 6,330,491) and further in view of Edelson et al. (U.S. 5,737,539). Claims 51-78 and 88 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenblum (U.S. 6,529,801) in view of NCVHS (<http://www.ncvhs.gov/970416w2.htm>). Claims 89, 12, 13, and 91 have been rejected under 35

U.S.C. 103(a) as being unpatentable over Goetz et al. (U.S. 6,421,650) in view of Simcox et al. (U.S. 5,992,890). Applicant traverses these rejections for at least the following reasons.

### **35 U.S.C. § 101**

Claims 45-46 and 84-85 have been rejected under 35 U.S.C. §101. Applicant has amended claims 45-46 and 84-85 as suggested by the Examiner. Therefore, Applicant respectfully requests that said rejection be withdrawn.

### **35 U.S.C. § 102**

Claims 79-84 and 86-87 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,529,801 (“Rosenblum”). Applicant respectfully traverses this rejection for at least the following reasons.

According to 102(e), a person shall be entitled to a patent unless:

the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the application for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Anticipation under 35 U.S.C. §102 requires the cited art teach every aspect of the claimed invention. *See, M.P.E.P. §706.02(a)*. In other words, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a

single prior art reference." *See, M.P.E.P. §2131 citing Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).*

Claims 79-84 and 86-87 all require that a reason why the drug is to be dispensed as written be entered or received. Rosenblum fails to teach this element. The Examiner has stated that she interprets "the DAW code to be a form of 'reason.'" The Examiner's interpretation is incorrect. DAW stands for Dispense As Written. According to column 9, lines 31-36, as cited by the Examiner, Rosenblum teaches that "the prescriber indicates whether the prescription is to be 'dispensed as written,' i.e., an equivalent generic drug can not be substituted in place of the specific brand of drug for which the prescriber has written." Rosenblum may teach that a prescriber can choose between brand and generic drugs, however, Rosenblum fails to teach that the reason that a drug be "dispensed as written" is entered or received. As described in paragraphs 48-50 of Applicant's specification, there may be numerous reasons that a drug be dispensed as written such as the patient has requested the brand drug, or no generic is available, or the generic drug may be unsuitable for the patient, none of which is contemplated by Rosenblum. Further, the Examiner has acknowledged that Rosenblum "does not expressly disclose entering via the electronic prescription creation device a reason why the drug is to be dispensed as written." *See* Office Action at page 20. Therefore, Rosenblum fails to teach all of the elements of claims 79-84 and 86-87 and the rejection under 35 U.S.C. §102(e) should be withdrawn.

### **35 U.S.C. §103(a)**

35 U.S.C. §103(a) recites:

[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this

title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 706.02(j).

**a) Goetz and Lion**

Claims 1-2, 9, 14-21, 24-27, 29-31, 33-34, 36, 38-40, 42-50 and 90 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Goetz (U.S. 6,421,650) in view of Lion (U.S. 6,330,491). The Examiner has attempted to combine the teachings of Goetz with those of Lion. Such a combination is improper. Applicant respectfully disagrees for at least the following reasons.

Independent claims 1, 20, 25, 36, 38, 45, 47, and 49 all require transmission of a prescription and/or override or the reason for the override over a network directly to a prescription processor. As acknowledged by the Examiner, Goetz does not disclose transmitting information directly to a prescription processor. *See* Office Action at page 6. The Examiner has relied on Lion as teaching a direct transmission of prescription information to a prescription

processor. Lion is directed to a “network of interactive, self-service, Rx drug vending machines or kiosks that are each adaptable to contain an inventory of, for example, 200 to 1600 different drugs, as may be currently obtained directly from a local storefront, mail order, or ‘cyber’ pharmacy.” Column 1, lines 50-56. While Lion may contemplate the receipt by a pharmacist of a prescription from a physician, the teachings of Lion should not be combined with those of Goetz.

As Applicant previously explained, Goetz teaches a medication management system that requires a patient component, physician component, and a pharmacist component. *See abstract*; column 4, lines 22-24. The patient component provides the link between the physician’s component and the pharmacist’s component. *See column 8, lines 59-62*. The physician can enter a prescription for a patient by using the physician’s component. *See column 10, lines 48-50*. The prescription is then downloaded to the patient component. *See column 11, lines 35-38*. “The patient then takes the patient component to the pharmacist who then transfers the patient data from the patient component 104 to the pharmacist’s PC component for execution of the prescription.” Column 11, lines 40-43. Thus, there is no need for direct communication between a prescriber and a prescription processor because of the existence of the patient’s component. One of skill in the art would not be motivated to combine the teachings of Goetz with those of Lion because Goetz requires a patient component. Direct communication between the physician component and pharmacist component would eliminate the function of the patient component, an essential feature of Goetz. Thus, the teachings of Goetz teach away from such a combination.

Further, independent claims 20 and 36 require that a reason or motive for overriding the drug use evaluation alert be entered or received. The Examiner has stated that column 16, lines 42-47 of Goetz teaches “a specific caution note” and the Examiner interprets “a specific caution

note" to be a form of motive. *See* Office Action at page 6. The Examiner has misconstrued the teachings of Goetz. Goetz states that "if the drug is prescribed, a specific caution note would preferably be generated and downloaded to the patient component describing the interaction." Column 16, lines 44-47. Goetz says that the interaction can be described in the caution note. Goetz says nothing about the reason for overriding a drug use evaluation alert being entered or received. Thus, Goetz fails to teach this limitation found in Applicant's invention, therefore, the §103 rejection should be removed.

Because Goetz should not be combined with Lion and because Goetz and Lion do not teach all of the elements of Applicant's invention, Applicant respectfully traverses the 35 U.S.C. § 103 (a) rejection with respect to claims 1-2, 9, 14-21, 24-27, 29-31, 33-34, 36, 38-40, 42-50 and 90 for at least the foregoing reasons. Further, the Examiner has rejected claims 3-8, 22 and 28 as being unpatentable over Goetz (U.S. 6,421,650) in view of Lion (U.S. 6,330,491) and further in view of Edelson (U.S. 5,737,539). As these claims ultimately depend from independent claims 1, 20, and 25, the arguments made with respect the independent claims are reasserted and Applicant respectfully requests that said rejections be withdrawn.

**b) Rosenblum and NCVHS**

Claims 51-78, 85, and 88 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rosenblum (U.S. 6,529,801) in view of NCVHS (<http://www.ncvhs.hhs.gov/970416w2.htm>). All of the aforementioned claims relate to dispensing a drug "as written" and the reason why the drug is to be dispensed as written. Reference to Applicant's disclosure demonstrates that Applicant's use of the term "as written" refers to the dispensing of brand name drugs versus generic drugs. The Examiner has acknowledged that Rosenblum fails to "expressly disclose entering via the electronic prescription

creation device a reason why the drug is to be dispensed as written.” *See* Office Action at page 20. The Examiner has relied on NCVHS to fill the deficiency of Rosenblum. However, any motivation or suggestion to combine NCVHS with Rosenblum is lacking.

The NCVHS reference is a letter to the National Center for Health Services in which NCPDP responds to questions raised by the National Committee on Vital and Health Statistics. The National Committee on Vital and Health Statistics asked “what medical/clinical codes and classifications do you use in administrative transactions now?” In response, NCPDP stated that DAW codes are used in the pharmaceutical industry and affect the actual payment of claims. Rosenblum, however, is directed to “an automatic prescription drug dispenser including a remote dispenser, a prescription entry system, and a communications network.” *See* abstract. Thus, Rosenblum is directed to a drug dispenser, not to the payment of claims as is the NCVHS reference. Thus, neither reference suggests that it should be combined with the other. Further, the motivation to combine cannot be found in the knowledge of one of skill in the art at the time of Applicant’s invention. According to the NCVHS reference, DAW codes have been in existence since at least 1997. Thus, DAW codes had been in existence for years when the Rosenblum application was filed. Given that Rosenblum fails to teach entering or receiving the reason a drug should be dispensed as written further suggests that one of skill in the art would not have been motivated to combine the teachings of Rosenblum with the NCVHS reference at the time of Applicant’s invention.

Because Rosenblum should not be combined with NCVHS, Applicant respectfully traverses the 35 U.S.C. § 103(a) rejection with respect to claims 51-78, 85, and 88 for at least the foregoing reasons.

**c) Goetz and Simcox**

Claims 89, 12, 13, and 91 have been rejected under 35 U.S.C. § 103 as being unpatentable over Goetz (U.S. 6,421,650) in view of Simcox (U.S. 5,992,890). Applicant traverses this rejection for at least the following reasons.

Claims 13, 89, and 91 all require the creation of a paper prescription printed with a printer in communication with the electronic prescription creation device which contains the override. Claim 12 has been canceled. The Examiner has noted that Goetz does not disclose creating a paper prescription printed with a printer in communication with the electronic prescription creation device. *See* Office Action at page 26. The Examiner has asserted that Simcox teaches this element. However, neither Goetz nor Simcox teach an element of Applicant's invention: that the paper prescription contain the override. Goetz and Simcox fail to teach all of the elements of Applicant's invention; therefore, the rejection under 35 U.S.C. §103(a) with respect to claims 13, 89 and 91 should be withdrawn.

**Conclusion**

In light of the forgoing amendments and remarks, Applicant respectfully submits that the pending claims are in condition for allowance.

Respectfully Submitted,

  
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